

In Re. Patent Appln. of Hott, J.S. *et al.*  
Serial No. 10/005,512

Reply to the Official Action of February 26, 2003  
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APR 29 2003

## Remarks

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### I. Status and Nature of the Amendment

Claims 1-15 are presently pending. Claims 1 and 6 have been amended to delete the abbreviation of the nicotinic acetylcholine receptor. The recitation of this abbreviation is believed to be redundant in light of the claims' recitation of the receptor's name. The claims have additionally been amended to recite that the toxin being administered is a *muscle* toxin, in contrast to a neurotoxin, such as botox. Support for this recitation can be found at page 2, lines 8-11, wherein the specification discloses the administration of a toxin to muscle cells. No new matter has been introduced by this amendment.

### II. Response to Restriction Requirement

The Examiner has issued a requirement for restriction of the original claims, identifying two separate and distinct inventions:

Group I:	claims 1-11	drawn to a method of treating focal muscle spasm with an immunotoxin, classified in class 424, subclass 183.1
Group II:	claims 12-15	drawn to an immunotoxin, classified in class 530, subclass 391.7

Applicants herewith elect to prosecute the invention of Group I in the parent application.

Election is made with traverse. Applicants respectfully submit that a search of methods of treating focal muscle spasm with an immunotoxin (i.e., the invention of Group I) would unquestionably require searching the art pertaining to immunotoxins *per se* in order to determine whether any description of an immunotoxin discussed using the immunotoxin for treating focal muscle spasms. As such, Applicants submit that searching the inventions of both Group I and Group II in the prosecution of this application would

not involve any increased burden to the Examiner or the Office. The Examiner is respectfully requested to reconsider the necessity of the restriction requirement.

### **III. The Patentability of the Claimed Invention**

As the Examiner will appreciate, focal muscle spasms result from the undesired stimulation of muscle cells by nerve cells. Prior to the present invention, two distinct and independent approaches existed for treating focal muscle spasms:

- Transiently inhibiting the neurological enervation of the muscle cells; or
- Surgically reducing or removing cells of the involved muscle.

The use of neurotoxins to treat focal muscle spasms is exemplified by the ability of the neurotoxin “botox” to temporarily reduce the symptoms of focal muscle spasms (see Specification, pages 1-2). Botox inhibits the release of acetylcholine from the neuromuscular junction, resulting in a localized paralysis when minute doses are injected.

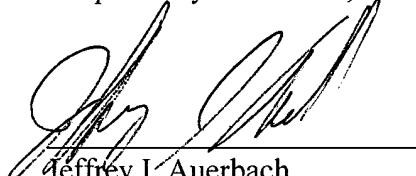
The use of surgery to treat focal muscle spasms is discussed in the introduction of Christiansen, S.P. *et al.* “Acute effects of the skeletal muscle-specific immunotoxin ricin-mAb 35 on extraocular muscles of rabbits,” *Invest Ophthalmol Vis Sci*. 2000 Oct;41(11):3402-9, a copy of which is enclosed.

The present invention presents a novel third approach to treating focal muscle spasms: i.e., using a toxin to accomplish a “chemo-surgical” reduction in the number of living muscle cells within the involved muscle. The present invention is thus directed to methods and compositions for killing muscle cells. It is more specific and long-lasting than procedures involving the transient inhibition of nerve cell stimulation; it is safer, less risky, and more precise than surgical procedures. Applicants respectfully submit that the claimed invention is distinct from, and patentable over, the methods of the prior art.

#### IV. Concluding Remarks

Applicants respectfully submit that the present application is in condition for Examination, and earnestly solicit early notice of favorable action. The Examiner is respectfully invited to contact the undersigned with respect to any issues regarding this application.

Respectfully Submitted,



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